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⑤④ **Buttoned device for the transvenous occlusion of intracardiac defects.**

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DE-A- 2 822 603
US-A- 3 874 388

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Description

The present invention relates to an intracardiac prosthesis, and more particularly, concerns a transvenously deliverable prosthesis for the occlusion of intracardiac defects as specified in the preamble of Claim 1. Such a device is known e.g. from US-A-3 874 388.

Intracardiac defects occur relatively uncommonly in children but can cause significant problems including congestive heart failure, pulmonary hypertension or even death. They are treated medically initially but quite frequently require surgical repair.

The surgical repair of intracardiac defects requires the use of general anesthesia, thoracotomy and heart-lung machine. It is associated with significant morbidity and mortality, pain for the child and a significant expense for the parents. For these reasons attempts were made before to close intracardiac defects without surgery. For example see King et al U.S. Pat. 3,874,388. Dr. King's device was a two disk device. Both disks were connected to a catheter. Since both disks needed to be introduced simultaneously, a large introducing sheath (7.5mm in diameter) was required, which made the application to children difficult. The release mechanism was also complex. Dr. King applied his device in a few adults. However the method was never popularized.

The late Dr. Rashkind invented an umbrella device with hooks on the inside. The umbrella was introduced by a long catheter in the distal to the defect chamber, it would open there and then would be pulled against the septal wall by the catheter till it was well hooked. Subsequently, it was released.

The method did not become popular, because it was associated with complications. Dr. Rashkind invented also a hookless two disk device. However details of the specifications are not known and none of the above devices was patented. We know though a great deal more about his double disk device, designed to occlude a vessel called patent ductus arteriosus. There are no hooks involved but a bulky delivery system, requiring a long sheath (11F or 3.7mm for a 17mm device) which is very large for a child.

The intracardiac prosthesis of the present invention provides the means of the transvenous, without surgery, occlusion of intracardiac defects. The occlusion is achieved by two independently buttoned components, the occluder and the counter-occluder or occluder holder as specified in Claim 1.

In the occluder of this invention, the polyurethane foam with the X shape wire skeleton is folded so that the skeleton wires become nearly parallel. Thus the occluder can be introduced through a 7F (2.3mm) or an 8F (2.7mm) long sheath. The foam has a diameter of 2mm, while the wire is size 0.018-0.025" (0.045-0.06cm). The wire is polytetrafluorethylene covered in order not to be thrombogenic. The occlud-

er is dipped into Heparin solution before the introduction. At the center of the occluder a 2mm long double loop is attached. The loop is closed by a 1mm diameter knot. In actuality this knot will be the "button" during the attachment with the counter-occluder.

Another aspect of the present invention is the counter-occluder, or occluder holder. It is rhomboid in shape, made also by 2mm thick polyurethane foam and a single 0.018" (0.045cm) wire of equal diameter to the occluder. Foam and wire are stitched together by a continuously run suture. A 2mm rubber piece of rhomboid shape is sutured at the center of the occluder-holder. By applying two sutures along the rubber piece, the foam is covering the rubber, so there is no friction during the introduction and the advancement of the occluder-holder in the long sheath. A further aspect of the present invention is the release or loading wire. It comprises a polytetrafluorethylene coated hollow wire of a 0.028" (0.07cm) wire and a double 0.005" (0.017cm) Trilene thread, attached on the one end at already described occluder loop and tied on the other end of the hollow wire.

Trilene is a trademark and identifies a synthetic mono-filament fishing line of thread. The loading wire is used:

1. To pull the occluder against the septum.
2. To load the occluder-holder by threading the wire through the rubber center of the occluder-holder.
3. As the axis of the pushing catheter and the long sheath, so the occluder-holder is pushed and is buttoned securely against the occluder.
4. To release the device, by cutting its distal end, pulling the hollow wire over the double Trilene thread and then pulling the thread as a single strand.

In accordance with the principles of the present invention, the intracardiac prosthesis hereof has significant advantages over known devices and specifically the Rashkind device and the King et al '388 device. It is miniaturized in size, requires a 7F (2.3mm) or 8F (2.7mm) sheath in comparison to a 15F (5.0mm) sheath for the Rashkind device or a 23F (7.5mm) sheath for a King et al device. It does not utilize hooks so it is not traumatic to the endocardium, or the conduction system. It conforms with the overall applicability of this intracardiac device to small children.

FIG. 1. is a perspective view of the preferred embodiment of the intracardiac prosthesis part of the occluder, illustrated in the unfolded condition.

FIG. 2. is a perspective view of the preferred embodiment of the intracardiac prosthesis part of the occluder, illustrated in the folded condition, ready to be introduced in the long sheath.

FIG. 3. is a perspective view of the occluder connected through the central loop with the loading wire.

FIG. 4. is a perspective view of the intracardiac prosthesis part of the counter-occluder or occluder

holder.

FIG. 5. is a cross-sectional view of the intracardiac device part of the occluder, connected to the loading wire and occluding an atrial septal defect.

FIG. 6. is a cross-sectional view of the intracardiac device part of the occluder-holder as it is introduced into the long sheath, over the loading wire.

FIG. 7. is a cross-sectional view of the occluder and occluder-holder parts of the device buttoned together and occluding the atrial septal defect.

FIG. 8. is a cross-sectional view of the detachment of the intracardiac device in the heart and removal of the loading wire and the long sheath.

While this invention is satisfied by embodiments in many forms, a preferred embodiment of the invention will herein be described in detail, with the understanding that the present disclosure is not intended to limit the invention to the embodiment illustrated. Referring to the drawings, and FIG. 1 in particular, there is illustrated the preferred intracardiac prosthesis part, the occluder 10, of the present invention in the unfolded condition.

The occluder 10 is made by polyurethane foam 16 lining 2mm thick, with a diameter of 10mm more than the diameter of the defect to be occluded. A polytetrafluorethylene coated wire skeleton 12 is introduced into the foam in an X shape and securely stitched to the foam by continuous and interrupted sutures.

A double loop thread or threaded loop 14 is securely attached at the center of the wire skeleton. The length of the loop is 2mm and is closed by a knot 18 of 1mm in diameter.

In FIG. 2 which illustrates the occluder 10 folded, it becomes obvious how by applying gentle pressure on the edges of the wire skeleton between the thumb and the index finger, the occluder can be introduced into the long intravascular sheath 40. The long sheath can be as small as 7 or 8F in diameter so the device can be introduced through the vessels of small children. Turning now to FIG. 3, the occluder 10 is connected to loading wire 28. The loading wire 28 consists of hollow wire 30 of a 0.028" (0.07cm) polytetrafluorethylene coated wire and the double 0.005" (0.013cm) Trilene mono-filament thread 32. The mono-filament thread 32 is passed through the "button" loop 14 attached to the occluder 10 and then through the hollow wire 30 in a double fashion. (FIG. 3 and 6). Mono-filament thread 32 is tightened several times at distal end 36, of the loading wire 28, so it is stretched inside the hollow wire 30.

A 3cm thread end 38 is left after the knot at the distal end 36 in the mono-filament thread 32, to facilitate the future introduction of the occluder-holder 20 over the wire 28. The loading wire 28 serves several purposes as it has been described before, pulling the occluder 10 against the septum, serving as the loading axis of the occluder-holder 20 and finally incorporating the release mechanism of the intracardiac de-

vice.

FIG. 4 describes the occluder-holder 20 which is also made by 2mm thick foam 22. The length of the occluder-holder 20 is selected as equal to length of the occluder 10. Skeleton 26 is made by 0.018" (0.045cm) polytetrafluorethylene coated wire to avoid clot formation. Wire 26 and foam 22 are stitched together by continuous and interrupting sutures.

On the center of the occluder-holder 20 a 2mm rubber rhomboid piece 24 is sutured. It serves several purposes. Firstly allows the occluder-holder 20 to be moved on the loading wire 28 axis without danger of dislodgement. Secondly it has elastic properties, so it is distended to allow the button knot 18 through. Thirdly it serves as the button-hole, so that it does not allow the knot 18 to un-button after detachment, thus holding the occluder 10 and occluder-holder 20 together.

Two stitches sutured along the rubber button allow the rubber 24 to be covered by foam 22. Thus, the friction is minimized during the introduction and the advancement into the long sheath 40.

FIG. 5 describes the introduction and the positioning of the occluder 10 inside the heart. The folded occluder is introduced as described before into the long sheath 40. A 7F end-hole catheter 34 is introduced over the loading wire 28 into the long sheath 40 and it is pushing the occluder 10 till it exits in the cardiac chamber distant to the cardiac defect. After the occluder 10 comes out from the long sheath 40, it is automatically unfolded and pulled gently with the loading wire 28 against the septal wall where the occluder is loosely attached.

FIG. 6 describes the introduction of the occluder-holder 20 inside the long sheath 40. The loading wire 28 is threaded through the center of the rubber piece 24 of the occluder-holder. The occluder-holder 20 is then advanced over the loading wire 28 and it is introduced into the long sheath 40. The 7F end-hole catheter 34 is introduced over the loading wire 28, pushing the occluder-holder, till it exits the long sheath 40 in the proximal to the defect cardiac chamber.

FIG. 7 illustrates the attachment of the occluder 10 to the occluder-holder 20. The occluder-holder has exited the sheath 40 and is pushed by the end-hole catheter 34 in a parallel fashion to the defect and the occluder, but still on the loading wire 28 axis. The loading wire is pulled gently, while the occluder-holder 20 is pushed by the end-hole catheter 34 and the end of the sheath 40. The actual "button" process involves the entry of the knot 18 of the occluder loop 14 into the rubber center 24 of the occluder-holder and the attachment by the "valve" like action.

FIG. 8 illustrates the detachment. The end of the loading wire 28 is cut. A sterilized pair of small pliers is used to cut the end of the hollow wire 30 and the tightened double 0.005" (0.017cm) mono-filament

thread 32 which are located outside the body. Thus they become detached from each other and they are removed with the following mechanism:

The hollow wire 30 is pulled out over the double 0.005" (0.0127cm) mono-filament thread 32. The thread 32 is subsequently pulled out as a single strand, so that the device is detached inside the heart after the defect is occluded. The present invention provides a percutaneous deliverable intracardiac prosthesis, suitable for treatment of various intracardiac defects, including atrial septal defect, ventricular septal defect and cardiac defects as parts of more complex lesions.

As an aid to correlating the terms of the claims to the exemplary drawing, the following catalog of elements and steps is provided:

10	occluder	
12	skeleton	
14	thread loop	
16	polyurethane disc	20
18	knot	
20	counter-occluder or occluder holder-rhomboid	
22	polyurethane disc - (holder)	
24	rubber piece - rhomboid	
26	skeleton	25
28	loading wire	
30	hollow wire or tube	
32	Trilene thread	
34	catheter	
36	Distal end	30
38	Thread end	
40	long sheath	

Claims

1. An intracardiac percutaneously deliverable device for the repair of heart defects comprising a pair of cooperating foldable members each comprising a wire skeleton and polyurethane foam, and a loading wire (28) including a hollow wire (30), characterized in that the first of said cooperating foldable members is an occluder (10), said occluder including:
 - i. a foldable foam polyurethane disk (16) with
 - ii. polytetrafluorethylene coated wire skeleton (12) in the form of an "X" sutured to the foam disk, and
 - iii. a thread (14) sutured to the center of the wire skeleton,
 - iv. said thread formed into a loop with
 - v. a knot (18) closing the loop remote from the skeleton, whereas the second of said cooperating foldable members is an occluder-holder (20), said occluder-holder including:
 - i. a foldable foam polyurethane rhomboid disc with
 - ii. a single wire skeleton sutured to the

rhomboid disc, and

iii. a rubber piece (24) sutured at the center of the rhomboid disc, said loading wire (28) including:

- i. a polytetrafluorethylene coated hollow wire (30), and
- ii. a long thread, said loading wire (30) being capable of being pierced through an opening in the occluder-holder in its rubber piece, said long thread extending
 - i. through the hollow wire,
 - ii. through the thread loop of the occluder, and
 - iii. back through the hollow wire;
 so arranged and constructed that
 - i. the occluder-holder (20) may be pushed by an end-hole catheter (34) along the loading wire (28) towards the occluder (10) at the distal end of the said loading wire (28) and
 - ii. pulling on the loading wire while holding catheter (34) in a counteracting manner will pull the knot (18) through the rubber piece (24) of the occluder-holder (20) thereby
 - iii. buttoning the occluder (10) to the occluder holder (20).

Patentansprüche

1. Ein endokardiales Gerät zur Heilung der Herzerkrankungen, das perkutan eingeführt wird und aus zwei zusammenarbeitenden faltbaren Gliedern besteht. Ein jedes Glied besteht aus einem Drahtgestell und aus Polyurethane. Das Gerät enthält auch einen Lastdraht (28), der einen gehöhlten Draht (30) umfaßt, und prägt sich dadurch aus, daß das erste der besagten zusammenarbeitenden faltbaren Glieder ein Verschließer (10) ist, der besagte Verschließer umfaßt:
 - i. eine faltbare Scheibe aus Polyurethane (16) mit
 - ii. Drahtgestell (12), das mit TEFLON belegt ist, die Form eines "X" hat und mit der Scheibe zusammengenäht ist und
 - iii. einen Faden (14), der mit dem Mittelpunkt des Drahtgestells zusammengenäht ist,
 - iv. den besagten Faden, der zu einer Schleife geformt ist mit
 - v. einen Knoten (18), der die Schleife entfernt von dem Drahtgestell schließt, während das zweite der besagten zusammenarbeitenden faltbaren Gliedern ein Halter (20) des Ver-

schließers ist,

der besagte Halter des Verschließers umfaßt:

i. eine faltbare rautenförmige Scheibe aus Polyurethane mit

ii. ein einzelnes Drahtgestell, das mit der rautenförmigen Scheibe zusammenge- 5
näht ist,

iii. ein Stück aus Gummi (24), das mit dem Mittelpunkt der rautenförmigen Scheibe zusammenge- 10
näht ist,

der besagte Lastdraht (28) umfaßt:

i. einen gehöhlten Draht (30), der mit TEFLON belegt ist und

ii. einen langen Faden, 15
der besagte Lastdraht (28) kann durch eine Öffnung des Halters (20) gedrun-
gen werden und zwar durch eine Öff-
nung seines Stücks aus Gummi,

der besagte lange Faden dringt

i. durch den gehöhlten Draht 20

ii. durch die Schleife des Verschlie-
ßers und

iii. wieder durch den gehöhlten
Draht,

das Gerät hat solche Anordnung, 25
daß

i. der Halter des Verschließers
durch einen Katheter (34)
entlang dem Lastdraht (28) zu
dem Verschlie ßer (10) gescho- 30
ben werden kann,

ii. Wenn der Lastdraht gezogen
wird, wird der Knoten (18) auch
durch das Stück aus Gummi
(24) des Halters (20) gezogen 35
vorausgesetzt, daß der Kathe-
ter (34) festgehalten ist, Auf die-
se Weise,

iii. werden der Verschlie ßer (10)
und der Halter des Verschlie- 40
ßers (20) miteinander geknüpft.

Revendications

1. Un appareil intracardiaque, qui est introduit à tra- 45
vers la peau pour la réparation des defaillances
cardiaques. Cet appareil comprend une paire de
membres coopérés et pliants. Chacun de ces
membres comprend un squelette de fil metallique 50
et polyurethane. L' appareil comprend aussi un fil
métallique de chargement (28), qui contient un fil
métallique perforé (30) et qu'il se caractérise par
le fait que le premier de membres dites est un
obstrueur (10), l'obstrueur dit contient: 55

- i. un disque pliant de polyurethane (16) avec
ii. un squelette de fil métallique couvert de TE-
FLON (12) dont la forme est un "X" et qui est

cousu au disque et

iii. un fil (14) cousu au centre du squelette de
fil métallique,

iv. le fil dit, formé comme un noeud coulant
avec

v. un noeud (18), qui ferme le noeud coulant
loin du squelette, taudis que le deuxième de
ces membres dites est un support du obs-
trueur (20), le support du obstrueur dit
contient:

i. un disque rhomboïdal et pliant, de polyu-
rethane avec

ii. un squelette de fil métallique particulier,
qui est cousu au disque rhomboïdal, et

iii. une pièce de caoutchouc (24), qui est
cousue au centre du disque rhomboïdal,
le fil métallique de chargement (28) dit
centient:

i. un fil métallique perforé (30) couvert
de TEFLON, et

ii. un fil long,

le fil métallique de chargement (28) dit
est capable de pénétrer à travers une
ouverture du support du obstrueur,
l'ouverture se trouve à la pièce de
caoutchouc,

le fil long dit, pénètre:

i. à travers le fil métallique perforé,

ii. à travers le noeud conlant du obs-
trueur, et

iii. eucore une fois à travers le fil
métallique perforé,

l'appareil est arrangé et construit
de manière que:

i. le support du obstrueur (20)
pent être poussé par un cathe-
ter (34) le long de fil métallique
de chargement (28) vers le obs-
trueur (10) et

ii. en tirant le fil métallique de
chargement peudant que le
cathéter (34) est tenu fixe, le
noeud (18) sera tiré à travers la
pièce de caoutchouc (24) du
support du obstrueur (20) et de
cette manière

iii. le obstrueur (10) et le support
du obstrueur (20) sont boutto-
nès mutuellement.



